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10/582,531	06/21/2007	Rodrigo Franco	AM102286	9924

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
04/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,531	FRANCO ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/28/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 28 January 2009 has been entered in full. Claims 7, 11-17, and 19-47 have been cancelled and claims 2, 6, 10, and 18 have been amended.

Claims 1-6, 8-10, and 18 are under examination.

Claim Objections

The objection of claims 2, 4, 6, 8 and 18 has been withdrawn because Applicants have removed the limitation reciting “essentially” in claims 2 and 6.

Specification

The objection to the title is withdrawn since Applicants have provided a new title reciting "Novel Sodium Channel" to "Murine Type III Sodium Channel Compositions and Methods of Use Therefor."

Information disclosure statement

The information disclosure statement filed 01/29/2009 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Although Applicants have provided dates for the references in the IDS filed 01/28/2009, the references that include GenBank® Accession Numbers NM 006922, GenBank® Accession Numbers AF225986, GenBank® Accession Numbers NM 013119, GenBank® Accession

Numbers NM 018732, GenBank® Accession Numbers NM 013199 have not been considered by the Examiner because the nucleic acid sequences for these references have scrambled sequences. Please submit a courtesy copy of the references and a new PTO-1449.

Rejections Withdrawn

35 USC § 101- Utility

Applicant's response and argument filed on 01/29/2009 have overcome the rejection of claims 1-6, 8-10, and 18 under 35 USC 101. Applicant indicates that Example 3 and Figure 3 in the specification provide evidence that this claimed sodium channel has sodium channel activity (see page 8 of the response). The rejection of claims 1-6, 8-10, and 18 under 35 USC 101 has been withdrawn.

35 USC § 101-non-statutory subject matter

Applicant's amendment made to claim 10 filed on 01/29/2009 have overcome the rejection of claim 10 under 35 USC 101. Applicants have amended the claim with the limitation reciting "isolated". The rejection of claim 10 under 35 USC 101 has been withdrawn.

35 USC § 112, Second paragraph

Applicant's amendment made to claim 18 filed on 01/29/2009 have overcome the rejection of claim 18 under 35 USC 112, Second paragraph. Applicants have amended the claim with the addition of the limitation reciting "isolated" and the removal of the limitation "a subunit polypeptide activity in a cell". The rejection of claim 18 under 35 USC 112, Second paragraph, has been withdrawn.

35 USC § 112, First paragraph (Written Description)

Applicant's amendment made to claim 18 filed on 01/29/2009 have overcome the rejection of claim 18 under 35 USC 112, First paragraph (Written Description). Applicants have amended the claim with the removal of the limitation "an amount of a $mNa_v1.3$ α subunit polypeptide modulator effective to modulate an activity of the $mNa_v1.3$ α polypeptide". The rejection of claim 18 under 35 USC 112, First paragraph, has been withdrawn.

Rejection Maintained

Claim Rejections - 35 USC § 112, First paragraph (Enablement)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Although Applicant has overcome the utility rejection for claims 3 and 8, claims 3 and 8 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *an isolated sodium channel type III α subunit (mNa_v 1.3 α subunit) polypeptide, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:2, and an isolated mNa_v 1.3 α subunit nucleic acid molecule that encodes the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2*, does not reasonably provide enablement for *an isolated mNa_v 1.3 α subunit polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO:2 and a fragment of the mNa_v 1.3 α subunit nucleic acid molecule comprising the nucleotide sequence encoding the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2*. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include: (1) Nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the breath of the claims, (7) the quantity of experimentation needed, (8) relative skill of those in the art.

Nature of the invention and breath of the claims

The claimed invention is drawn to an isolated mNa_v 1.3 α subunit polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO:2 and a fragment of the mNa_v 1.3 α subunit nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1 encoding the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2. The invention is excessively broad because the recitation of claims 3 and 8 encompass a large number of polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO:2 and fragments of the mNa_v 1.3 α subunit nucleic acid molecule that encodes the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2. Although claims 3 and 8 recite that the claimed polypeptide and fragment include certain amino acid residues, the recitation of claims 3 and 8 includes a large number of peptides because the specification does not provide any functional identifying characteristics associated the claimed polypeptide of claim 3 and fragments of claim 8. For instance, the recitation of claim 3 and 8 does not provide any functional limitations associated with the claimed polypeptide.

The amount of direction or guidance present

Applicants' disclosure is limited to the functional and structural characterization of the full length mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2 and full length mNa_v 1.3 α subunit nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1 encoding the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2 (Example 2, pages 77-80; Example 3, pages 80-81).

However, the specification does not provide guidance or direction regarding any functional characteristics for the isolated mNa_v 1.3 α subunit polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO:2 and a fragment of the mNa_v 1.3 α subunit nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1 encoding the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2.

In addition, the specification does not provide any guidance regarding which residues are critical to retain the functional characteristics of the full-length sodium channel subunit of SEQ ID NO:2 in order to make the claimed mNa_v 1.3 α subunit polypeptide. More specifically, the specification does not provide any information regarding which residues can be deleted or substituted while maintaining the biological activity of the polypeptide in the absence of a functional limitation for the claimed mNa_v 1.3 α subunit polypeptide.

Working Examples

Although Applicant has provided examples for the functional and structural characterization of the full length mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2 and full length mNa_v 1.3 α subunit nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1 encoding the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2 (Example 2, pages 77-80; Example 3, pages 80-81) and the comparison for the sequence of mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2 with the mNa_v 1.3 α subunit of human, mouse, and rat, the specification does not provide any methods or working examples for the isolated mNa_v 1.3 α

subunit polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO:2 and a fragment of the mNa_v 1.3 α subunit nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1 encoding the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2.

The quantity of experimentation needed

It would require undue experimentation for one of skill in the art to be able to use the claimed treatment method because the specification and claims have not provided the functional characteristics for the isolated mNa_v 1.3 α subunit polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO:2 and a fragment of the mNa_v 1.3 α subunit nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1 encoding the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2. A large amount of experimentation would be required because one of skill in the art would not know which residues are critical to retain the functional characteristics of the full-length sodium channel subunit of SEQ ID NO:2 in order to make the claimed mNa_v 1.3 α subunit polypeptide. More specifically, the specification does not provide any information regarding which residues can be deleted or substituted while maintaining the biological activity of the polypeptide in the absence of a functional limitation for the claimed mNa_v 1.3 α subunit polypeptide.

Thus one of skill the art would not be able to use the claimed isolated mNa_v 1.3 α subunit polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO:2 and fragment of the mNa_v 1.3 α subunit nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1 encoding the mNa_v 1.3 α subunit polypeptide of SEQ ID NO:2 because the specification has not provided enough information.

New Ground of Rejection

Claim Rejections - 35 USC § 112 (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection. The amended claim represents a departure from originally filed. Although Applicant has pointed out the location for the support for the amended claim 18 in the specification (Example 3, page 81), the Examiner has determined that the support is not sufficient. Claim 18 now recites “depolarizing voltage sufficient to cause the channel to open and a sodium current to pass through the channel”. However, Example 3 in specification does not provide any support for these claim amendments. The specification at page 81 discloses sodium currents at different depolarizing voltages. For instance, the recitation of depolarizing voltages in the ranges of -80mV to 50mV would overcome the rejection.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
March 31, 2009

/Robert Landsman/
Primary Examiner, Art Unit 1647